510(k) Summary

FEB 19 2013

Device: Intradermal Adapter

Company Name:
WEST PHARMACEUTICAL SERVICES, INC.
101 Gordon Dr.
Lionville, PA 19341

Contact Person:
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Director of Regulatory Affairs
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Preparation date: 19 November 2012

Classification:

Classification name:	Syringe, Piston (Accessory)
Trade name:	Intradermal Adapter
Common/usual name:	Intradermal Adapter (ID Adapter)
Product Code:	FMF
Regulation No.:	21 CFR 880.5860
Class:	II
Panel Identification:	General Hospital

Predicate Devices: K941657 BD-Microfine, Ultrafine; and Allergy Syringe

Device Description:

The Intradermal Adapter consists of a single injection molded part manufactured from a medical grade polycarbonate. The Intradermal Adapter is a piston syringe accessory which is designed for use with 1ml allergy syringes with ½ inch (27g), (28g), (29g) needles, which are commonly used for intradermal injections given with a traditional Mantoux technique.

The Intradermal Adapter has been designed to snap-fit on to the end of the syringe forming an injection guide to control the depth and angle of needle insertion exposing only the minimal needle length required to perform a successful intradermal injection. The Intradermal Adapter is provided sterile in an individually packaged configuration.

Indications for Use:

The Intradermal Adapter is an accessory to a 1 ml, ½ inch fixed-needle allergy syringe indicated for use as a guide for performing intradermal injections.

Technological Characteristics and Substantial Equivalence:

The Intradermal Adapter utilized as an accessory to the piston syringe has the same intended purpose and principle of operation as the predicate device with respect to performing an injection below the surface of the skin including intradermally and is therefore substantially equivalent to the cleared device referenced: K941657 (BD Microfine, Ultrafine, and Allergy Syringe).

Performance Testing:

Performance testing including bench, animal and simulated use was conducted to assess the safety and effectiveness of the Intradermal Adapter for the stated indications for use. Results of performance testing demonstrated that the Intradermal Adapter used as an accessory to the piston syringe is safe and effective in administering intradermal injections.

Conclusion:

Comparative analysis of the technological characteristics between the proposed and predicate device and results of verification testing performed demonstrate that the subject device is substantially equivalent to the legally marketed predicate device. Any differences between the proposed and predicate device do not raise any additional concerns regarding safety and effectiveness; therefore the Intradermal Adapter used as an accessory to the disposable allergy syringe may be considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 19, 2013

Mr. Kevin Lentz
Director of Regulatory Affairs
West Pharmaceutical Services, Incorporated
101 Gordon Drive
Lionville, Pennsylvania 19341

Re: K123588
Trade/Device Name: Intradermal Adapter
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: November 19, 2012
Received: November 21, 2012

Dear Mr. Lentz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

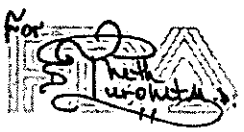
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123588

Device Name: Intradermal Adapter

Indications for Use:

The Intradermal Adapter is an accessory to a 1 ml, ½ inch fixed-needle allergy syringe indicated for use as a guide for performing intradermal injections.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123588